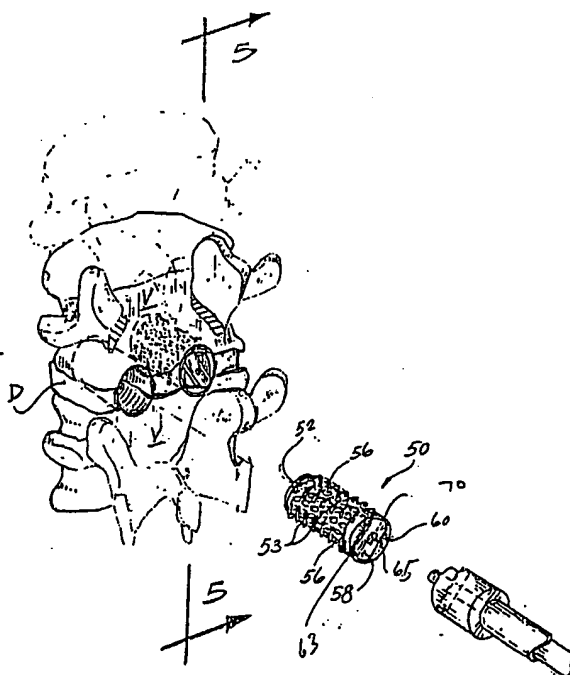


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁴ : A61F 2/00, 4/00, E21B 10/00	A1	(11) International Publication Number: WO 89/12431 (43) International Publication Date: 28 December 1989 (28.12.89)
(21) International Application Number: PCT/US89/02526 (22) International Filing Date: 13 June 1989 (13.06.89) (30) Priority data: 205,935 13 June 1988 (13.06.88) US (71)(72) Applicant and Inventor: MICHELSON, Gary, Karlin [US/US]; 438 Sherman Canal, Venice, CA 90291 (US). (74) Agent: SCHELLIN, Eric, P.; 2001 Jefferson Davis Highway, Suite 301, Crystal Plaza 1, Arlington, VA 22202 (US). (81) Designated States: AT (European patent), AU, BB, BE (European patent), BG, BR, CH (European patent), DE (European patent), DK, FI, FR (European patent), GB (European patent), HU, IT (European patent), JP, KP, KR, LU (European patent),		NL (European patent), NO, RO, SE (European patent), SU. Published <i>With international search report.</i>

(54) Title: THREADED SPINAL IMPLANT**(57) Abstract**

An artificial spinal implant (50) is disclosed which when placed between two adjacent vertebrae directly participates and is incorporated in the ensuing fusion. Instrumentation and procedure is also disclosed.



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Background

The present invention relates to an artificial fusion implant to be placed into the intervertebral space left after the removal of a damaged spinal disc.

5 The purpose of the present invention is to provide an implant to be placed within the intervertebral disc space and provide for the permanent elimination of all motion at that location. To do so, the device is space occupying within the disc space, rigid, self-stabilizing to
10 resist dislodgement, stabilizing to the adjacent spinal vertebrae to eliminate local motion, and able to intrinsically participate in a vertebral to vertebrae bony fusion so as to assure the permanency of the result.

At present, following the removal of a damaged
15 disc, either bone or nothing is placed into the space left. Placing nothing in the space allows the space to collapse which may result in damage to the nerves; or the space may fill with scar tissue and eventually lead to a reherniation. The use of bone is less than optimal in that
20 the bone obtained from the patient requires additional surgery and is of limited availability in its most useful form, and if obtained elsewhere, lacks living bone cells, carries a significant risk of infection, and is also limited in supply as it is usually obtained from accident
25 victims. Furthermore, regardless of the source of the bone, it is only marginal structurally and lacks a means to either stabilize itself against dislodgement, or to stabilize the adjacent vertebrae.

A review of related prior art will demonstrate
30 the novelty of the present invention.

There have been an extensive number of attempts to develop an acceptable disc prothesis (an artificial disc). Such devices by design would be used to replace a damaged disc and seek to restore the height of the
35 interspace and to restore the normal motion of that spinal joint. No such device has been found that is medically acceptable. This group of prosthetic or artificial disc replacements, seeking to preserve spinal motion and so are different from the present invention, would include:

flexible disc implant.

Patent No. 4,349,921 KUNTZ - describing a flexible disc replacement with file like surface projections to discourage device dislocation.

5 Patent No. 4,309,777 PATIL - describing a motion preserving implant with spiked outer surfaces to resist dislocation and containing a series of springs to urge the vertebrae away from each other.

10 Patent No. 3,875,595 FRONING - describing a motion preserving bladder like disc replacement with two opposed stud-like projections to resist dislocation.

Patent No. 2,372,622 FRENCH (FASSIO) - describing a motion preserving implant comprising complimentary opposed convex and concave surfaces.

15 In summary then, these devices resemble the present invention only in that they are placed within the intervertebral space following the removal of a damaged disc. In that they seek to preserve spinal motion, they are diametrically different from the present invention
20 which seeks to permanently eliminate all motion at that spinal segment.

A second related area of prior art includes those devices utilized replace essentially wholly removed vertebrae. Such removal is generally necessitated by
25 extensive vertebral fractures, or tumors, and is not associated with the treatment of disc disease. While the present invention is to be placed within the disc space, these other vertebral devices cannot be placed within the disc space as at least one vertebrae has already been
30 removed such that there no longer remains a "disc space." Furthermore, these devices are limited in that they seek to perform as temporary structural members mechanically replacing the removed vertebrae (not a removed disc), and do not intrinsically participate in supplying osteogenic
35 material to achieve cross vertebrae bony fusion.

Therefore, again unlike the present invention which provides for a source of osteogenesis, use of this group of devices must be accompanied by a further surgery consisting of a bone fusion procedure utilizing conventional
40 technique. This group consisting of vertebral struts

rather than disc replacements would include the following:

Patent No. 4,553,273 WU - describing a turnbuckle like vertebral strut.

5 Patent No. 4,401,112 REZAIAN - describing a turnbuckle like vertebral strut with the addition of a long stabilizing staple that spans the missing vertebral body.

10 Patent No. 4,554,914 KAPP - describing a large distractible spike that elongates with a screw mechanism to span the gap left by the removal of an entire vertebrae and to serve as an anchor for acrylic cement which is then used to replace the missing bone (vertebrae).

15 Patent No. 4,636,217 OGILVIE - describing a vertebral strut mechanism that can be implanted after at least one vertebrae has been removed and which device consists of a mechanism for causing the engagement of screws into the vertebrae above and the vertebrae below the one removed.

20 In summary then, this group of devices differs from the present invention in that they are vertebral replacements struts, do not intrinsically participate in the bony fusion, can only be inserted in the limited circumstances where an entire vertebrae has been removed from the anterior approach, and are not designed for, or intended to be used for the treatment of disc disease.

25 A third area of prior art related to the present invention includes all devices designed to be applied to one of the surfaces of the spine. Such devices include all types of plates, struts, and rods which are attached by hooks, wires and screws. These devices differ
30 significantly from the present invention in that they are not inserted within the disc space, and furthermore do not intrinsically participate in supplying osteogenic material for the fusion.

35 Therefore, with these devices where permanent spinal immobilization is desired an additional surgery consisting of a spinal fusion performed by conventional means or the use of supplemental methylmethacrylate cement is required. Such devices applied to the spine, but not within the disc space, would include the following:

40 Patent No. 4,604,995 - STEPHENS - describing a

"U" shaped metal rod attached to the posterior elements of the spine with wires to stabilize the spine over a large number of segments.

5 Patent No. 2,677,369 - KNOWLES - describing a metal column device to be placed posteriorly along the lumbar spine to be held in position by its shape alone and to block pressure across the posterior portions of the spinal column by locking the spine in full flexion thereby shifting the maximum weight back onto the patient's own
10 disc.

Other devices are simply variations on the use of rods (e.g. Harrington Luque, Cotrel-Dubosset, Zielke), wires or cables (Dwyer), plates and screws (Steffee), or struts (Dunn, Knowles).

15 In summary, none of these devices are designed or can be used within the disc space, do not replace a damaged disc, and do not intrinsically participate in the generation of a bony fusion.

Another area of related prior art to be
20 considered is that of devices designed to placed within the vertebral interspace following the removal of a damaged disc, and seeking to eliminate further motion at that location.

Such a device is contained in Patent No.
25 4,501,269 BAGBY - describing an implantable device and limited instrumentation. The method employed is as follows: a hole is bored transversely across the joint and then a hollow metal basket of larger diameter than the hole is then pounded into the hole and then filled with the bone
30 debris generated by the drilling.

While the present invention (device, instrumentation, and method) may appear to bear some superficial resemblance to the BAGBY invention, it is minimal, while the differences are many fold and highly
35 significant. These differences include the following:

1. Safety - The present invention provides for a system of completely guarded instrumentation so that all contiguous vital structures (e.g. large blood vessels, neural structures) are absolutely protected. Said
40 instrumentation also makes overpenetration by the drill

impossible. Such overpenetration in the cervical spine, for example, would result in the total paralysis or death of the patient. In the thoracic spine, the result would be completer paraplegia. In the lumbar spine, the result would be paraplegia or a life-threatening perforation of the aorta, vena cava, or iliac vessels. The present invention is atraumatically screwed into place while the BAGBY device, in contradistinction, is pounded into position. BAGBY describes that the implant is significantly larger in size than the hole drilled and must be pounded in. This is extremely dangerous and the pounding occurs directly over the spinal cord which is precariously vulnerable to percussive injury. Furthermore, while it is possible, for example in the lumbar spine, to insert the present invention away from the spinal cord and nerves, the BAGBY device must always be pounded directly towards the spinal cord.

Furthermore, since the BAGBY device is pounded into a smooth hole under great resistance, and lacking any specific design features to secure it, the device is highly susceptible to forceful ejection which would result in great danger to the patient and a clinical failure. The present invention, in contradistinction, is securely screwed into place, and possesses highly specialized locking threads to make accidental dislodgement impossible. Because of the proximity of the spinal cord, spinal nerves, and blood vessels, any implant dislodgement as might occur with the BAGBY device might have catastrophic consequences.

2. Broad applicability. - The BAGBY device can only be inserted from the front of the vertebral column, however, the present invention can be utilized in the cervical, thoracic, and lumbar spine, and can be inserted from behind (posteriorly) in the lumbar spine. This is of great importance in that the purpose of these devices is in the treatment of disc disease and probably greater than 99 percent of all lumbar operations for the treatment of disc disease are performed from behind where the present invention can easily be utilized, but the BAGBY device, as per his description, cannot.

3. Disc removal - The BAGBY invention requires

the complete removal of the disc prior to the drilling step, whereas the present invention eliminates the laborious separate process of disc removal and efficiently removes the disc and prepares the vertebral end plates in a single step.

4. Time required - The present invention saves time over the BAGBY invention in that time is not wasted laboring to remove the disc prior to initiating the fusion. Also, since with the present invention the procedure is performed through a system of guarded instrumentation, time is not wasted constantly placing and replacing various soft tissue retractors throughout the procedure.

5. IMPLANT STABILITY - Dislodgement of the implant would be a major source of device failure (an unsuccessful clinical result), and might result in patient paralysis or even death. As discussed, the BAGBY device lacks any specific means of achieving stability and since it is pounded in against resistance to achieve vertebral distraction, it is susceptible to forceful dislodgement by the tendency of the two distracted vertebrae, to return to their original positions squeezing out the device. The present invention however is screwed into place. As there is no unscrewing force present between the vertebrae and compression alone cannot dislodge the implant, the implant is inherently stable by its design. Furthermore, the threads of the present invention are highly specialized in that they are periodically interrupted such that the tail ends of each of the tabs so formed are blunted and twisted so as to resist accidental unscrewing. The removal of an implant with such "locking threads" requires the use of a special extractor included within the instrumentation. The stability of the present invention is still further enhanced, again in contradistinction to the BAGBY device, by the presence of a "bone ingrowth" surface texturing, which both increases the friction of the fit and allows for the direct growth of the vertebral bone into the casing of the implant itself.

6. Spinal stability - The present invention is not only self-stabilizing, it also provides stability to the adjacent vertebrae in at least three ways that the

BAGBY device cannot. First, the BAGBY device is placed transversely across the joint in the center, leaving both vertebrae free to rock back and forth over this round barrel shaped axis, much like a board over a barrel, being used for a seesaw.

Secondly, as the BAGBY device lacks any specific design features to resist sliding, it may actually behave as a third body allowing the translation of the vertebrae relative to the device and to each other.

Thirdly, any device can only provide stability if it remains properly seated. The present invention is inherently stable, and therefore assures that it will stabilize the adjacent vertebrae; rather than, as with the BAGBY device, where the instability of the spine to be treated may instead cause a dislocation of the implant, with further loss of spinal stability.

7. The collapse of the interspace - While both the present invention and the BAGBY device can be fabricated to withstand the compression forces within the interspace, the interspace may nevertheless collapse under the superincumbent body weight as the implant settles into the vertebral bone. This is related to the load of per unit area. Again the present invention is superior to the BAGBY device in at least four ways. First, the present invention offers considerably greater surface area to distribute the load. Secondly, while the BAGBY device is placed centrally, the present device is placed bilaterally where the bone tends to be more cortical and much stronger out towards the rim. Thirdly, the present invention supports the load achieving an "I" beam effect, whereas the BAGBY impland does not. Fourthly, it is not pressure alone that causes the collapse of the bone adjacent to the implant, but also bony erosion that is caused by the motion under pressure of the implant against the bone. As discussed in item #6 above, the present invention alone is highly resistant to such motion, again diminishing the likelihood of erosion and interspace collapse.

8. Bone ingrowth surface texturing - The present invention has a surface treatment of known and conventional technology to induce the growth of bone from the vertebrae

directly into the casing material of the implant itself. The BAGBY device has no similar feature.

5 9. Fusion mass - The BAGBY invention calls for removing the disc and then drilling a hole between the adjacent vertebrae. The bony debris so generated is then put into the device. The present invention takes a core of pure bone producing marrow from the iliac crest, and then by use of a special press forcibly injects the device with an extremely dense compressed core of that osteogenic material until the material itself virtually extrudes from every cell of the implant.

10 10. The probability of achieving fusion - The fusion rate within the spine is known to be related directly to the amount of exposed vascular bone bed area, the quality and quantity of the fusion mass available, and the extent of the stabilization obtained with all other factors being half constant. It would then be anticipated, that the fusion rate would be superior with the present invention as compared to the BAGBY device, because of optimal implant stability (#5), optimal spinal stability (#6), bone ingrowth surface treatment (#8), superior fusion mass (#9), and the greater exposed vertebral bony surface area (#7).

25 The last area of prior art possibly related to the present invention and therefore, to be considered related to "BONY INGROWTH", and patents either describe methods of producing materials and or materials or devices to achieve the same. Such patents would include:

30 Patents No. 4,636,526 (DORMAN), No. 4,634,720 (DORMAN), No. 4,542,539 (ROWE), No 4,405,319 (CONSENTINO), No. 4,439,152 (SMALL), No. 4,168,326 (BROEMER), No. 4,535,485 (ASHMAN), No. 3,987,499 (SCHARBACH), No. 3,605,123 (HAHN), No. 4,655,777 (DUNN), No. 4,645,503 (LIN), No. 4,547,390 (ASHMAN), No. 4,608,052 (VAN KAMPEN), No. 4,698,375 (DORMAN), No. 4,661,536 (DORMAN), No. 3,952,334 (BOKROS), No 3,905,047 (LONG), No. 4,693,721 (DUCHEYENE), No. 4,070,514 (ENTHERLY).

40 However, while the present invention would utilize bone ingrowth technology, it would do so with conventional technology.

In summary then, the present invention, instrumentation, and method, alone provides for a one stage discectomy, fusion, and interbody internal spinal fixation; that being performed more quickly, with greater safety, and more affectively, for all of the aforementioned reasons than is possible with any other known art.

Brief Summary of the Invention

The present invention comprises a series of artificial implants, the purpose of which is to participate in, and directly cause bone fusion across an intervertebral space following the excision of a damaged disc. Such implants are structurally load bearing devices, stronger than bone, capable of withstanding the substantial forces generated within the spinal interspace. Such device have a plurality of macro sized cells and openings, which can be loaded with fusion promoting materials, such as autogenous bone, for the purpose of materially influencing the adjacent vertebrae to perform a bony bond to the implants and to each other. The implant casing may be surface textured or otherwise treated by any of a number of known technologies to achieve a "bone ingrowth surface" to further enhance the stability of the implant and to expedite the fusion.

Further, said devices are so configured and designed so as to promote their own stability within the vertebral interspace and to resist being dislodged, and furthermore, to stabilize the adjacent spinal segments.

The apparatus for preparing the vertebrae for insertion of the implant is also disclosed, such instrumentation and method allowing for the rapid and safe removal of the disc, preparation of the vertebrae, performance of the fusion, and internal stabilization of the spinal segment.

Discussion of the Instrumentation

The concept of performing various aspects of this surgery are not entirely new. Drills are frequently placed through hollow, tubular guards to protect the adjacent soft tissues. A set of instruments developed by Ralph Cloward utilizes such a tubular drill guard on a loarger scale, for the purpose of drilling into the cervical spine. However,

this inventor is unaware of any set of instruments, system, or procedure designed to allow the entire surgical procedure beyond the initial exposure, to be performed blindly and with complete safety through a fixed sheath apparatus. Specific design features which combine to make this uniquely possible are as follows:

1. The availability of the specific implant.
2. The end of all the penetrating instrumentation is blunt faced.
3. All of the instruments have been stopped out at a predetermined depth to avoid overpenetration.
4. The design of the external sheath conforms to the spatial limitations of the specific surgical site.
5. The design and use of a second or inner sheath allows for the difference in size between the inside diameter of the outer sheath, and the outside diameter of the drill itself. This difference being necessary to accommodate the sum of the distraction to be produced, and the depth of the circumferential threading present of the implant.
6. A specially designed drill bit with a central shaft recess allows for the safe collection of the drilling products, which can then be removed without disturbing the outer sheath by removing the drill bit and inner sheath as a single unit.
7. A specially designed trephine for removing a core of bone slightly smaller in diameter than the internal diameter of the implant cavity itself, however of a greater length.
8. A specially designed press for forcefully compressing and injecting the long core of autogenous bone into the implant, such that it extrudes through the implant itself.
9. A specially designed driver extractor, which attaches to the implant and allows the implant to be either inserted or removed without itself dissociating from the implant, except by the deliberate disengagement of the operator.

Objects of the Present Invention

It is an object of the present invention to

provide an improved method of performing a discectomy, a fusion, and an internal stabilization of the spine, and specifically, all three of the above simultaneously and as a single procedure.

5 It is another object of the present invention to provide an improved method of performing a discectomy, a fusion, and an internal stabilization of the spine, which is both quicker and safer than is possible by previous methods.

10 It is another object of the present invention to provide an improved method of performing a discectomy, a fusion, and in internal stabilization of the spine, to provide for improved surgical spinal implants.

 It is another object of the present invention to
15 provide an improved method of performing a discectomy, a fusion, and an internal stabilization of the spine, which provides for an improved system of surgical instrumentation to facilitate the performance of the combined discectomy, fusion and internal spinal stabilization.

20 It is another object of the present invention to provide an improved method of performing a discectomy, a fusion, and an internal stabilization of the spine procedures.

 These and other objects of the present invention
25 will be apparent from review of the following specifications and the accompanying drawings.

Brief Description of the Drawings

 Figure 1 is a partial view of the vertebrae structure with the driver and outer sheath assembly of the
30 present invention.

 Figure 1A is a perspective view of the driver member for the outer sheath.

 Figure 2 is a perspective view of the outer sheath being inserted into the vertebrae structure.

35 Figure 3 is a perspective view of the outer sheath and inner sheath assembly, with the drill bit of the present invention.

 Figure 3A is a side sectional view of the collar and drill bit of Figure 3.

40 Figure 4 is a perspective view of a cylindrical

implant and vertebrae structure.

Figure 4A is a perspective view of one preferred embodiment of the implant.

Figure 4B is a cross sectional view of the
5 implant of Figure 4A.

Figure 4C is the driving and insertion equipment for the implant of Figure 4A.

Figure 4d is a side sectional view of the driver and implant between vertebrae.

10 Figure 5 is a sectional view of the vertebrae structure, taken along lines 5-5 of Figure 4.

Detailed Description of the Drawings

Referring to Figure 1 a vertebrae structure comprising two vertebrae V and a disc D between the two
15 vertebrae, is shown. A hollow tubular drill sleeve 10 has teeth 12 at its lower end. The sleeve 10 has an enlarged diameter upper portion 14.

A driver 16, shown in Figure 1A, consists of a solid tubular member 18 and an increased diameter head 20.
20 The external diameter of the solid tubular member 18 is slightly smaller than the inside diameter of the hollow tubular drill sleeve 10 and has a length that is substantially shorter than the overall length of the hollow tubular drill sleeve 10.

25 The drill sleeve 10 is made of metal in order to be driven into the vertebrae V and be held in place by the teeth 12 of the drill sleeve 10.

Referring to Figure 2 the drill sleeve 10 with the driver 16 installed is shown being driven into two
30 vertebrae V on either side of a disc D by hammer H.

Referring to Figure 3 and 3a the drill assembly is shown. In Figure 3 the drill sleeve 10 is illustrated in the two vertebrae V, straddelling the disc D.

The retaining sleeve 15 has an outside diameter
35 slightly smaller than the inside diameter of the drill sleeve 10, and a length substantially the same length as the drill sleeve 10. The retaining sleeve 15 has a collar 17 at its upper end for engaging the top of the drill sleeve 10.

40 The drill 22 comprises an upper portion 24, a

central recessed portion 26 and a lower cutting drill portion 28. The upper 24 and lower portion 28 of the drill 22 have the same outside diameter. The drill 24 has a collar 30 attached to the upper portion 24 of the drill 22.

5 The outside diameter of the drill 22 is slightly smaller than the inside diameter of the retaining sleeve 15. The length of the drill, from the collar 30 to the end of the drill bit, is such that a predetermined portion of the drill bit 22 extends beyond the end 29 of the sleeve
10 when fully inserted.

Referring to Figure 4, a cylindrical embodiment of the present invention is shown, one implant positioned in the opening in the vertebrae and disc formed by the drill 22, and a second implant shown prior to implantation.

15 The cylindrical implant 50 comprises a hollow tubular member which in the preferred embodiment is made of an ASTM surgically implantable material, and preferably Titanium. The cylindrical implant 50 is closed at one end 52 and open at the other end 54. The outer cylindrical
20 implant 50 has a series of macro-sized openings 56 through the side walls of the cylindrical member 50. A series of external threads 53 are formed on the circumference of the cylindrical implant 50. The threads 53 are locking threads having a series of interjections, the ends of which are
25 blunted and twisted so as to resist unscrewing.

The open end 54 of the cylindrical implant 50 has an internal thread 51 for receiving a complementary cap 52 which has an external thread 58 for engaging the internal threads 51 of the cylindrical member 50. The cap 52 has a
30 hexagonal opening 59 for use with an allen wrench for tightening the cap. A driver engaging element 70 is located on the rear surface 60 of the implant. The driver engaging element 70 comprises a raised rectangular portion 63 and a central threaded opening 65, for engaging the
35 driver apparatus, shown in Figure 4c and Figure 4d. The driving equipment 100 comprises a central tubular rod 102 having a thread fitting into opening 65 in the implant. An enlarged knurled knob 106 is affixed to the other end of the rod 102 for ease in turning. The central rod 102 is
40 enclosed within a hollow tubular member 108, having a

narrow lower portion 110 and an increased diameter upper portion 112. At the end of the lower portion 110 is a attachment member 114, having a generally rectangular depression 116 for complementing the driver engaging element 70 of the implant 50. A pair of handles 118 and 120 extend perpendicular from the upper position 112 of the tubular member 108 to assist in turning the driver 100.

The operation is performed in the following manner: (Example Lumbar Spine Posterior Approach) A skin incision is made directly over the interspace to be operated on. The dissection is carried down along side of the supraspinous and interspinous ligaments preserving those structures. A semi hemi laminotomy is performed at the upper level, removing sufficient bone to allow access into the interspace. The ligament flavum is removed and then the dural sac is protected by retracting it medially along with the traversing (inferior) nerve root. The superior nerve root or the root exiting beneath the pedicle at level above is visualized and protected.

At this time the drill sleeve 10 is placed into the spinal canal with both nerve roots directly inspected and protected. The drill sleeve 10 is imbedded by teeth 12 spanning the disc space from the midline over and it is seated into the two vertebrae V across the disc D space by using a driver 20. Once this is done, the driver 20 is removed and a retaining sleeve 15 is placed through the drill sleeve 10. Once sealed, sleeve 10 provides absolute protection to the dural sac and nerve roots as the remaining surgery is performed entirely through this sleeve.

The inner sleeve allows for the difference between the outside diameter of the drill 22 and the outside diameter of the threads 53 of the cylindrical implant 50. This then makes it possible to perform the entire operation through the Lumbar of the imbedded outer sleeve despite the differences in diameter between the drill and the implant.

A drill 22 is then placed in the retaining sleeve 17. The drill 22 is of such a length that it can not penetrate more than 28 millimeters beyond the end of the

drill sleeve 10. This, of course, could be varied and made smaller for enhanced safety. However at the present time 27 to 28 millimeters seems to be safe for probably 3 standard deviations of the population. The drill 22 is
5 attached to a power unit and the drilling takes place.

The recessed central area between the reduced portion 26 allows for the accumulation of the debris generated by the drilling. At this time, leaving the outer sleeve firmly embedded, the retaining sleeve 17 is removed
10 with the drill 22 as a single unit. All the vertebrae and disc debris that was generated during the drilling is contained within the recess and against the inside wall of the retaining sleeve 17 and can not come out within the spinal canal. Once the retaining sleeve 17 and drill 22 is
15 out of the patient's operative field, all of the material so generated can be removed.

The next step is that a screw tap is put doen through the drill sleeve 10. The tap also has a collar on it that will automatically stop the tap from extending
20 beyond 28 millimeters of penetration. The tap itself has a blunt nose that would also avoid any perforation. The tap is then removed. The tap size has deliberately been selected so that it's inner root diameter is 1.3 millimeters greater than the outside diameter of the drill
25 22. This insures that the interspace will be distracted by at least that much once the implant is placed. The tap has its outside diameter 1.2 millimeters greater than its root diameter. The tap is removed and the space is now prepared to accept the cylindrical implant 50.

30 The Implant 50 is prepared by utilizing the trephine, a hollow drill, to obtain a core of pure cancellous bone from the patients iliac crest of slightly smaller diameter than the internal diameter of the implant but approximately 6mm longer. The implant 50 is placed in
35 a press like device like an ammo loader and the bone graft measuring approximately 32 millimeters is then compressed into the hollow body of the implant (26mm) so that the bone graft fills the opening 54 and extends through the openings 56. The cap 60 is then screwed on to the implant 50 by use
40 of an allen driver/wrench and the device is ready for

implantation.

The inserter/remover is such that it lock onto the implant, so that the implant can be moved either clockwise or counter-clockwise, screwed or unscrewed. The implant itself has for its root diameter the same exact root diameter as the tap which as already noted is already 1.3 millimeters greater than the drill and has an outside diameter, 1.5 millimeters greater than its root. This is also .3 millimeters greater than the threads cut by the tap so that in inserting the device it is actually cutting through previously uncut bone helping to insure that it locks in firmly. The threads on the implant 50 are locking threads so that it is easier to screw the device in than for it to be unscrewed. However, with sufficient torque it is possible to extract the device if ones so desires.

Once the implant has been seated it is able to be inserted only 28 millimeters. Since the implant 50 is only 26 millimeters in length, this virtually guarantees that the implant 50 will be recessed into the vertebral bodies more than 2 millimeters and can not protrude into the spinal canal.

Similarly, the implants shown in Figure 4b can be implanted. The implant in Figure 4b is a modified solid, having extensive channelling throughout, and has no cap. A central opening 61 permits insertion of the bone graft material into the interior of the implant.

These implants have a surface configuration such as to induce bone ingrowth through the implant, and into the wall of the vertebrae in effect inducing fusion from one vertebrae in joint to the other, thereby eventually making the implant itself superfluous as the bone would do the work.

The implant itself, because of its being made of stronger material than bone, would provide structural support to the two vertebrae while awaiting bone ingrowth. Once the bone ingrowth occurred, however, the implant would be firmly and permanently fixed in place.

As shown in Figure 4, more than one implant is inserted into the disc space, thereby preventing the rocking motion that would result in the difficulties

referred to above in the discussion of the bagby patent.

While the invention has been described with regards to the preferred embodiment, it is recognized that alternative embodiment may be devised which would not depart from the present invention.

What I claim is:

1 1. A fusion implant comprising a cylindrical
2 member having an outside diameter larger than the space
3 between two adjacent vertebral to be fused and a series of
4 threads on the exterior of said cylindrical member for
5 engaging said vertebrae to maintain said implant in place.

1 2. The implant of claim 1 in which said
2 cylindrical member has a plurality of openings therein.

1 3. The implant of claim 1 in which the implant
2 is made from a material designed to promote bone ingrowth.

1 4. The implant of claim 1 in which said implant
2 has a hollow portion for receiving autogenous bone for
3 promoting bone ingrowth.

1 5. The apparatus of claim 4 in which said
2 implant has a removable cap for covering said hollow
3 portion.

1 6. The implant of Claim 1 in which said implant
2 has means for engaging a insertion/removal device for
3 inserting and removing said insert.

1 7. The implant of Claim 6 is which said engaging
2 means comprises a shoulder and threaded opening.

1 8. The implant of Claim 1 in which said threads
2 are locking threads.

1 9. The implant of Claim 1 in which said threads
2 are interrupted.

1 10. The implant of Claim 5 in which said cap has
2 a thread for screwing onto said hollow portion.

1 11. Apparatus for use in performing surgery for
2 fusing vertebrae comprising a rigid tubular member having

means at one end for engaging two adjacent bones.

1 12. The apparatus of claim 11 in which said
2 means for engaging said vertebrae comprises a plurality of
3 teeth.

1 13. The apparatus of claim 12 including a
2 removable internal hollow tubular sleeve.

1 14. The apparatus of claim 13 in which said
2 removable sleeve has a collar at one end larger than the
3 inside diameter of the tubular member.

1 15. A drilling member for use in a spinal
2 surgical procedure comprising a drill bit, said drill bit
3 having a narrowed portion between the lower and upper
4 portions of said drill bit.

1 16. The apparatus of claim 15 in which said
2 upper and lower portion of the drill bit on either side of
3 said narrowed portion are the same diameter.

1 17. The apparatus of claim 15 including an
2 increased diameter collar on the upper portion of said
3 drill bit.

1 18. The apparatus of claim 15 in which said
2 drill bit has an increase portion at its upper end at a
3 predetermined position for restricting penetration of said
4 drill.

1 19. Apparatus for use in performing surgery
2 comprising a rigid tubular member having means at one end
3 for engaging two adjacent vertebrae members; a removable
4 internal hollow tubular sleeve; a drill bit for use in a
5 surgical procedure, said drill bit having a narrowed
6 portion between the ends of said drill bit, the outside
7 diameter of said drill bit being slightly smaller than the
8 inside diameter of said removable sleeve.

1 20. The apparatus of claim 19 in which the
2 portions of said drill bit on either side of said narrowed
3 portion are the same diameter.

1 21. The apparatus of claim 19 in which said
2 drill has an increase diameter collar portion at its upper
3 end at a predetermined position for restricting penetration
4 of said drill bit.

1 22. The apparatus of claim 19 in which the
2 length of said drill from said increased diameter collar
3 portion is longer than the length of said tubular driving
4 member.

1 23. A method for removing the disc between two
2 adjacent vertebrae comprising inserting a tubular member
3 having means to engage two vertebrae into the vertebrae;
4 drilling the disc and a portion of the two adjacent
5 vertebrae through said tubular member; tapping the opening
6 formed by the drill in the disc to create a thread in the
7 vertebrae; inserting a cylindrical implant having
8 corresponding threads to those formed by the tap in the
9 vertebrae through the tubular member; and then removing
10 said tubular member.

1 24. The method of claim 23 in which said drill
2 has means associated therewith for limiting the depth of
3 the drilling.

1 25. The method of claim 23 in which the tubular
2 member has a inner removable sleeve.

1 26. The method of claim 23 in which the tubular
2 member is installed in said vertebrae by placing a driver
3 within said tubular member and hitting the driver with a
4 hammer.

1 27. The method of claim 23 in which said implant
2 is made of a material that promotes bone ingrowth.

1 28. An implant removal/insertion device for
2 inserting or removing an implant in the body of a patient
3 said implant having a generally cylindrical configuration,
4 a thread on its outside perimeter and a central threaded
5 portion, comprising a first tubular member having an
6 outside diameter and thread corresponding to the central
7 threaded portion of said implant; and an engaging means
8 for engaging a portion of the implant, whereby said
9 engaging means is fixed to said implant; said engaging
10 means being rotatable in relationship to said first tubular
11 member.

1 29. The apparatus of claim 28 in which said
2 implant has a shoulder and said engaging means comprises a
3 corresponding member for fixing to said shoulder.

1 30. The apparatus of claim 28 in which said
2 engaging means has handle means extending perpendicularly
3 from said engaging means for rotating said engaging means.

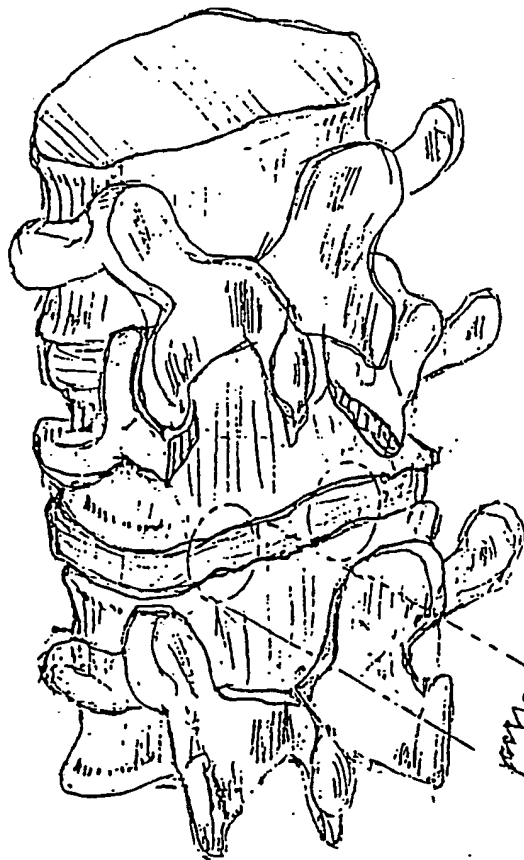
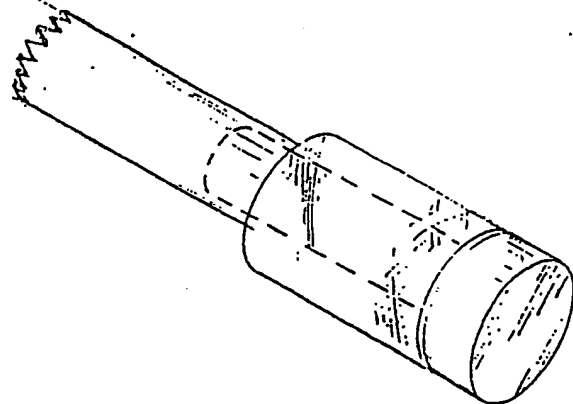
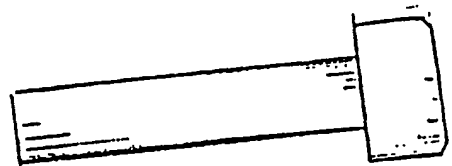


Fig. 1.

Fig. 1A.



- 2 / 6 -

fig. 2.

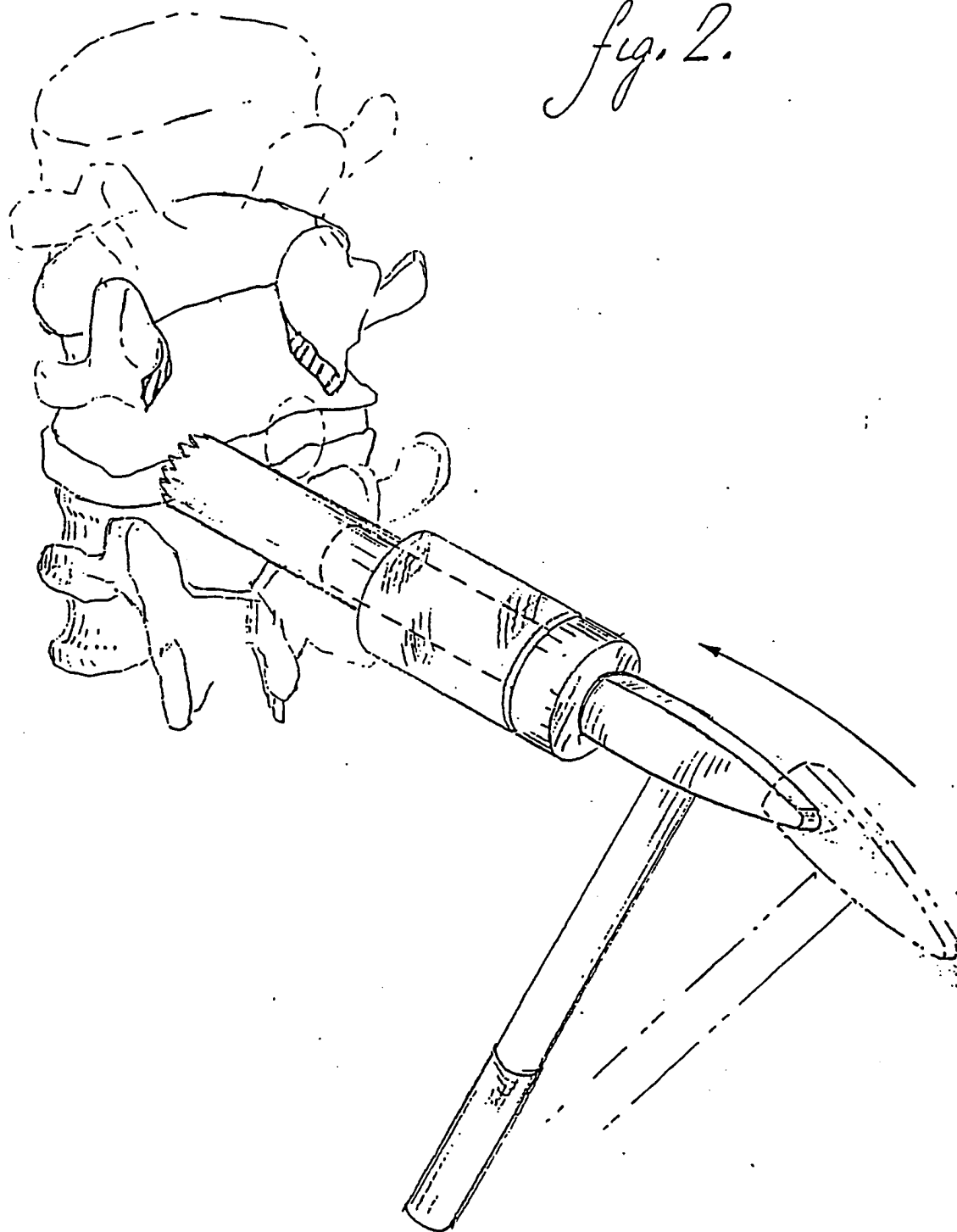


fig. 3.

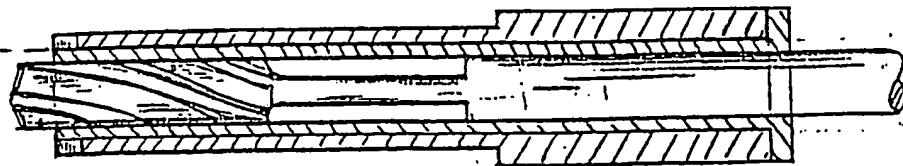
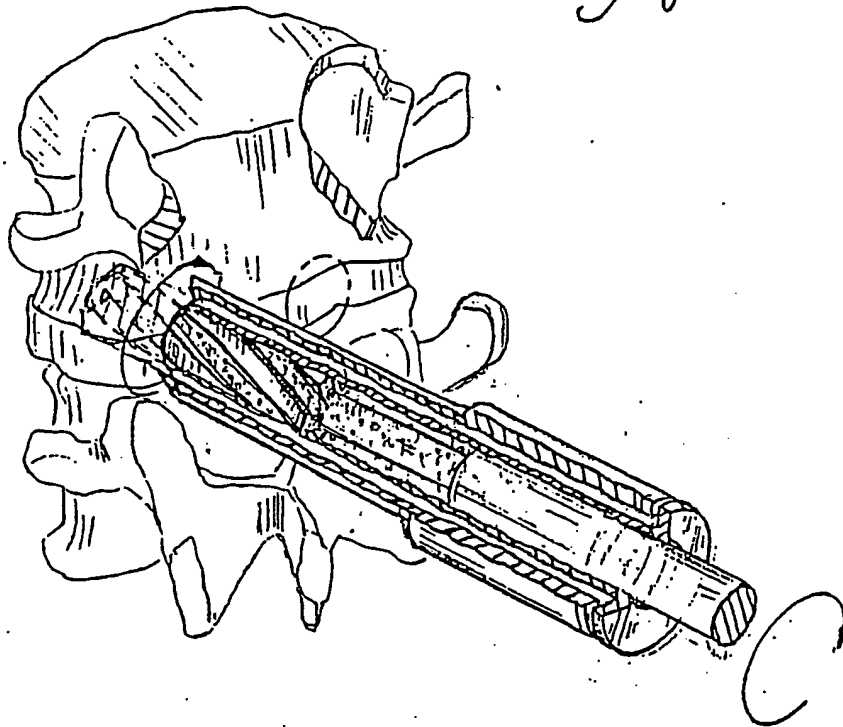
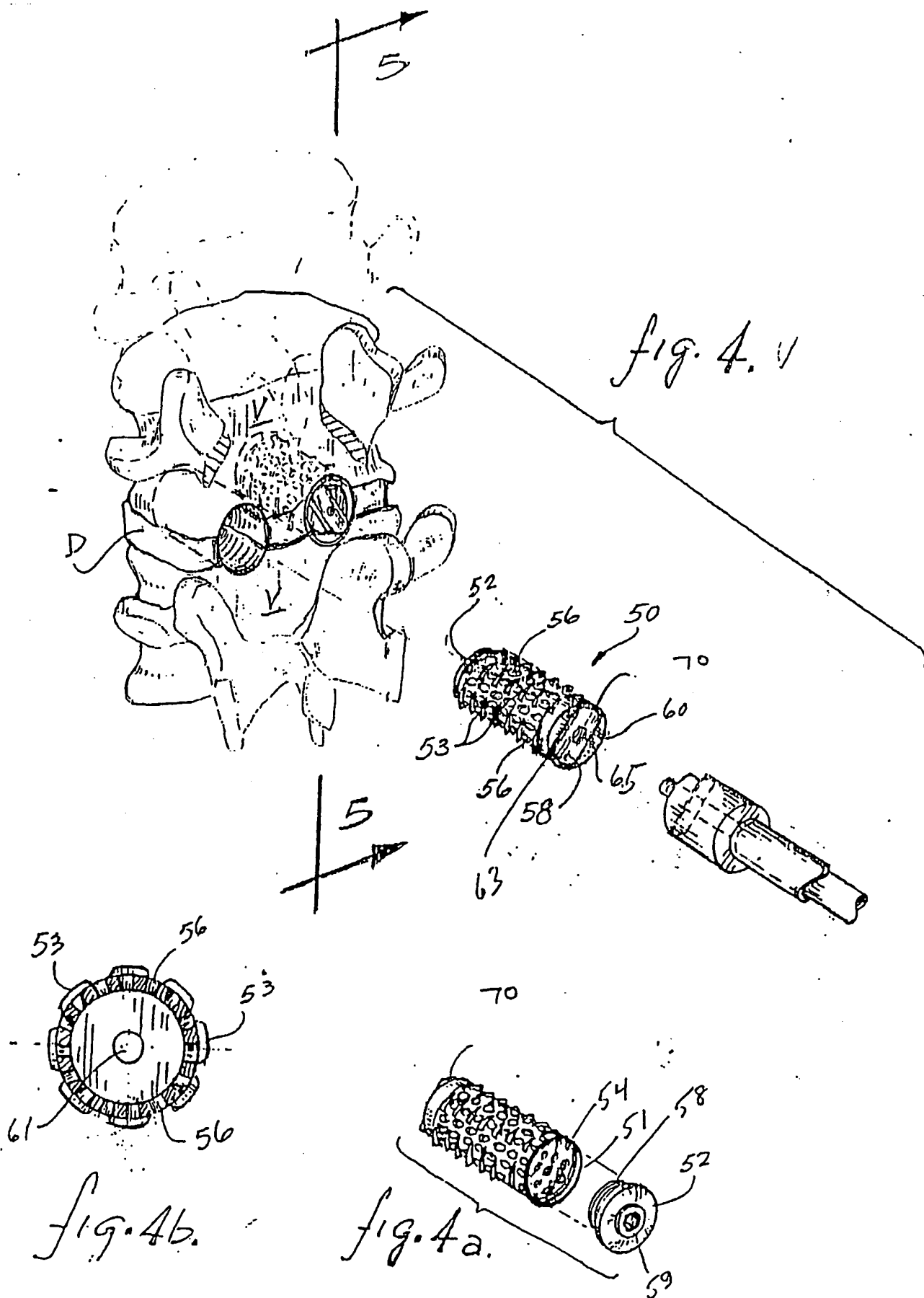
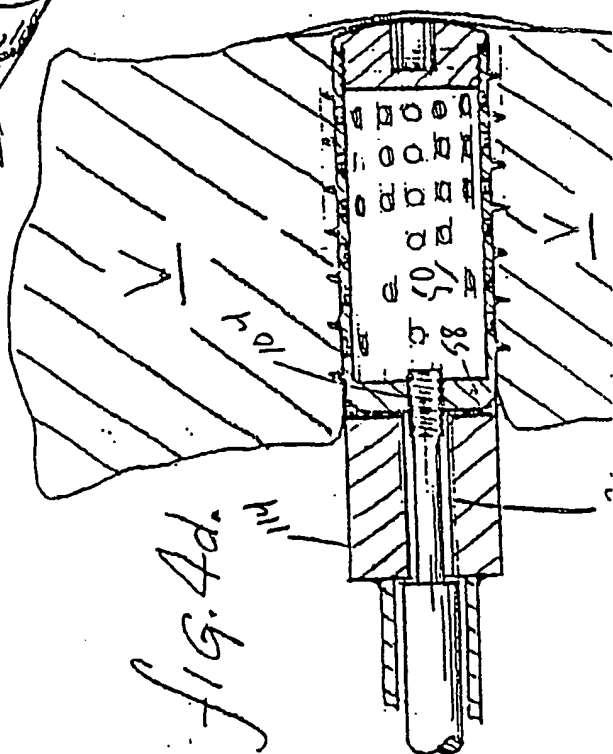
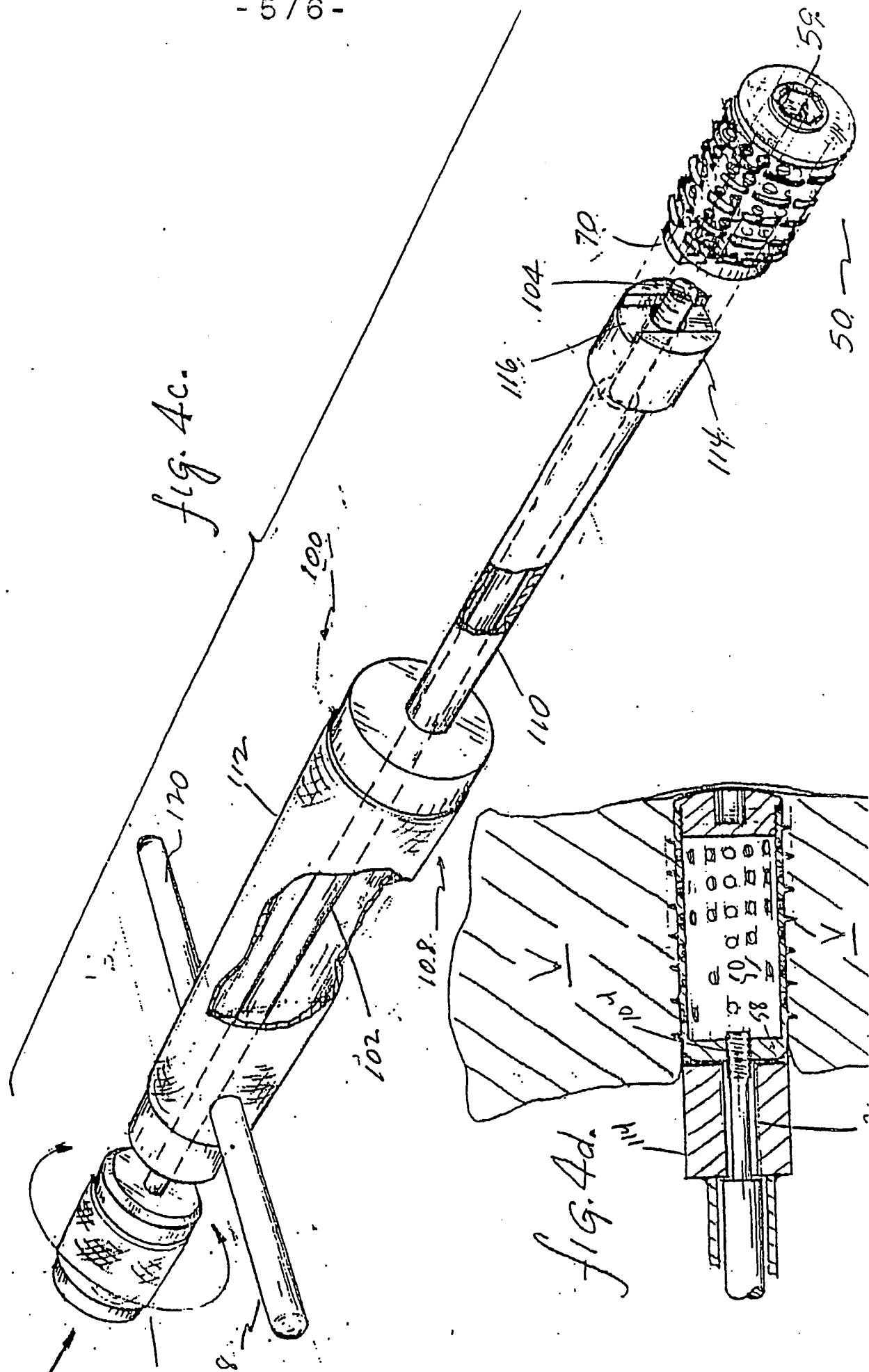
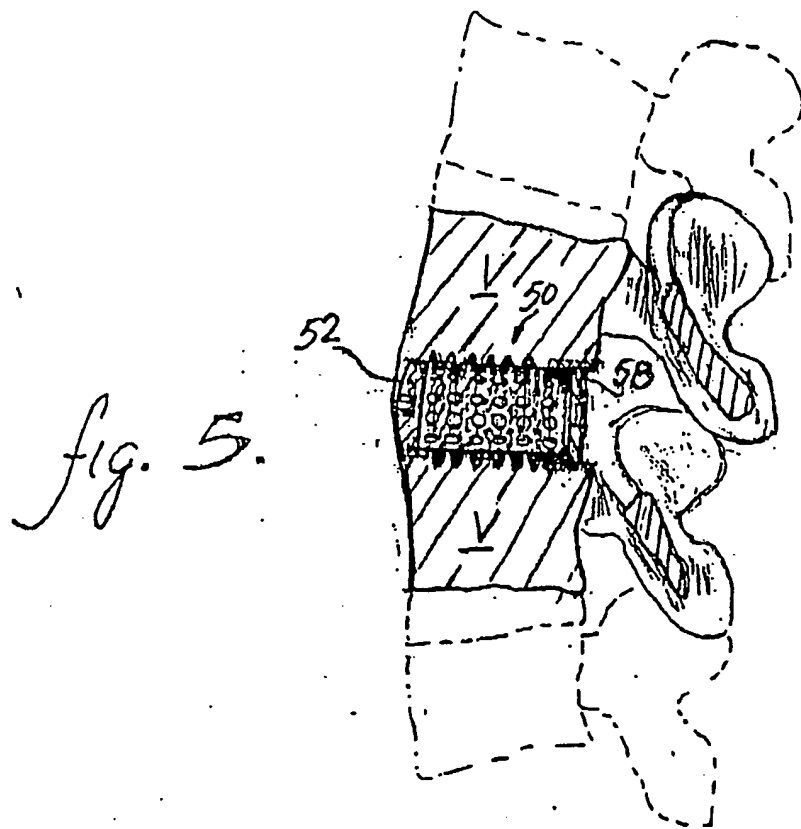


fig. 3A.







INTERNATIONAL SEARCH REPORT

International Application No. **PCT/US89/02526**

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC (4): A61F 2/00, A61F 4/00; E21B 10/00
U. S. Cl. 128/92YJ, 92YM; 623/17

II. FIELDS SEARCHED

Minimum Documentation Searched ⁷

Classification System	Classification Symbols
U.S.	128/92VT, 128/92YJ; DIG. 15/138, 139; 408/214, 217, 219; 128/92ZW, 92YQ, 92YG, 92YM, 92YC, 92YE; 623/16, 17, 18, 19, 20

Documentation Searched other than Minimum Documentation
to the Extent that such Documents are Included in the Fields Searched ⁸

III. DOCUMENTS CONSIDERED TO BE RELEVANT ⁹

Category *	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
Y	US, A, 4,501,269 (BAGBY) 26 February 1985 See the entire document.	1-10, 23-27
Y X	US, A, 4,328,593 (SUTTER ET AL.) 11 May 1982 See the entire document.	<u>1-10, 23-27</u> 11-12
Y	US, A, 4,259,072 (HIRABAYASHI ET AL.) 31 March 1981 See the entire document.	1-7
Y	US, A, 4,743,256 (BRANTIGAN) 10 May 1988 See the entire document.	1-5
Y	US, A, 4,349,921 (KUNTZ) 21 September 1982 See the entire document.	1-5
X Y	US, A, 4,059,115 (JUMASHEV ET AL.) 22 November 1977 See the entire document.	<u>11-13</u> 14, 19-22
X	US, A, 2,537,070 (LONGFELLOW) 09 January 1951 See the entire document.	11-14
X Y	US, SD, 257,511 (ZAHN) 11 November 1980 See the entire document.	<u>15, 17-18</u> 16

* Special categories of cited documents: ¹⁰

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search

22 August 1989

Date of Mailing of this International Search Report

05 OCT 1989

International Searching Authority

Signature of Authorized Officer

Michael G. Brown

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

X Y	US, A, 4,051,905 (KLEINE) 04 October 1977 See the entire document.	15, 17-18 16, 19-22
A	US, A, 4,423,721 (OTTE ET AL.) 03 January 1984 See the entire document.	28-30

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE ¹

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers _____, because they relate to subject matter ¹² not required to be searched by this Authority, namely:

2. ☐ Claim numbers _____, because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out ¹³, specifically:

3. ☐ Claim numbers _____, because they are dependent claims not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. ☒ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING ²

This International Searching Authority found multiple inventions in this international application as follows:

I. Claims 1-10, drawn to a fusion implant, classified in Class 128, subclass 92YM.

II. Claims 11-14 and 19-22, drawn to an apparatus for use in performing surgery for fusion, classified in Class 128, subclass 92YJ. (cont'd)

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application. **Telephone Practice**
2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

- ☐ The additional search fees were accompanied by applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.